

★ JAN 17 2019 ★

**UNITED STATES DISTRICT COURT
FOR EASTERN DISTRICT OF NEW YORK**

BROOKLYN OFFICE

IN RE RESTASIS (CYCLOSPORINE OPHTHALMIC
EMULSION) ANTITRUST LITIGATION

18-MD-2819 (NG) (LB)

THIS DOCUMENT APPLIES TO: ALL CASES

OPINION AND ORDER

GERSHON, United States District Judge:

In this multi-district litigation, plaintiffs have moved to compel from defendant Allergan production of documents that Allergan shared with two independent consultants, Robert Pollock of Lachman Consultant Services, Inc. and Timothy Hanford of ADC Strategies LLC.¹ Plaintiffs contend that Allergan waived its right to assert the attorney-client privilege over the documents because it shared them with these third parties. Defendant relies on two exceptions to the third-party waiver rule to argue otherwise. First, it asks the court to find that the input offered by Mr. Pollock and Mr. Hanford was necessary for Allergan's attorneys to provide informed legal advice. Second, Allergan argues that Mr. Pollock and Mr. Hanford were functionally equivalent to its own employees.

On December 19, 2018, I heard extensive oral argument on plaintiffs' motion. For the reasons stated below, the motion is granted.

¹ Plaintiffs also sought to compel the production of two categories of communications involving Allergan's citizen petitions. At a status conference on December 19, 2018, the parties agreed to continue to meet and confer regarding those issues and, if they do not reach a resolution, to provide the court with additional briefing. Therefore, this decision does not address that portion of plaintiffs' motion.

I. FACTUAL BACKGROUND

Allergan has submitted declarations from Damon Burrows, its Vice President and Associate General Counsel during the relevant period; Robert Lively, Allergan's Vice President of Global Government Affairs; and Christina Markus, a partner at King & Spalding, a law firm Allergan retained to provide legal advice concerning, among other things, regulatory issues. These declarations describe the roles that Mr. Pollock and Mr. Hanford played in responding to the draft guidance of the Food and Drug Administration (FDA), which contained recommendations to applicants seeking approval for generic versions of Restasis®, Allergan's branded version of cyclosporine ophthalmic emulsion. Allergan's responses to this draft guidance—which included filing comments and citizen petitions—are central to the plaintiffs' allegations in this litigation. *See In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135 (E.D.N.Y. 2018).

A. Robert Pollock of Lachman Consultant Services, Inc.

Mr. Pollock is the former Acting Deputy Director of the FDA's Office of Generic Drugs. In July 2013, Allergan retained Mr. Pollock as a consultant based on the recommendation of Mr. Burrows, who believed Mr. Pollock would help “ensure that Allergan's in-house and outside attorneys provided informed and effective legal advice regarding the FDA draft guidance and related documents.” Mr. Burrows and Ms. Markus “consider[ed] Mr. Pollock to have uniquely specialized knowledge and experience on FDA regulatory issues,” especially FDA draft guidance. Mr. Burrows believed that Mr. Pollock's knowledge “was different from what Allergan's employees and attorneys could have themselves provided.”

As an example of when Mr. Pollock's “specialized input” shaped her legal advice, Ms. Markus cites an email in which she shared with Allergan's legal team and Mr. Pollock a draft of

Allergan's comment on the FDA's draft guidance. She sent the email to "obtain[] Mr. Pollock's strategic advice" about the document so that she "could provide effective legal advice to Allergan and its in-house counsel."

According to Mr. Burrows and Ms. Markus, Mr. Pollock worked closely with Allergan's attorneys to determine its strategy regarding the FDA. They treated Mr. Pollock as they did any other Allergan employee; he was "an integral member" of their team. Mr. Burrows and Ms. Markus believed that confidential communications shared with Mr. Pollock would remain confidential, and Allergan's consulting agreement with Lachman Consultant Services required that the firm not disclose Allergan's confidential information.

B. Timothy Hanford of ADC Strategies LLC

After Allergan retained Mr. Hanford in August 2015, Mr. Lively recommended that Allergan's legal team work with him to respond to the FDA's draft guidance. Mr. Hanford had previously served as counsel to the U.S. House of Representatives' Ways and Means Committee and, according to Mr. Lively, had "many years of experience and deep knowledge about members of Congress and congressional and federal agency practices." Mr. Lively "consider[ed] Mr. Hanford to have uniquely specialized knowledge and experiences with government affairs involving health care." Although Mr. Hanford is a lawyer, he did not provide Allergan with legal advice. However, Mr. Lively considered Mr. Hanford "keenly aware of the type of information lawyers need to provide effective legal advice to a corporate client."

Mr. Lively, who is not a lawyer, forwarded emails containing privileged information from Allergan's attorneys to Mr. Hanford. Plaintiffs have highlighted two such emails, redacted versions of which were provided to the court. The first contains legal advice from Robert Bailey, Allergan's General Counsel, about an executive order relevant to the company's communications with the

FDA regarding cyclosporine ophthalmic emulsion. The second contains legal advice from three lawyers, including Mr. Bailey, concerning Allergan's August 2017 citizen petition. According to Mr. Lively, he forwarded these emails to Mr. Hanford so that Mr. Hanford could provide "strategic advice" to Mr. Lively and Allergan's counsel. Mr. Lively also sought Mr. Hanford's "reaction and input" regarding Mr. Bailey's advice to inform Mr. Lively's discussions with Mr. Bailey.

Ms. Markus and Mr. Lively explained that they worked with Mr. Hanford as they did with any other Allergan employee; he was an "important" or "integral" member of the team tasked with responding to the FDA and to Congress regarding Restasis®. They considered communications shared with Mr. Hanford confidential. The consulting agreement between Allergan and ADC Strategies required that ADC Strategies keep information it received from Allergan confidential.

II. ANALYSIS

The attorney-client privilege is meant "to encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice." *Upjohn Co. v. United States*, 449 U.S. 383, 389 (1981). "[T]he privilege exists to protect not only the giving of professional advice to those who can act on it but also the giving of information to the lawyer to enable him to give sound and informed advice." *Id.* at 390. In the case of corporations, the Supreme Court has held that communications between in-house counsel and a corporation's employees are privileged if they are intended to secure legal advice. *Id.* at 394.

Nonetheless, because "the privilege stands in derogation of the public's 'right to every man's evidence,' and as 'an obstacle to the investigation of the truth,'" it must be "strictly confined within the narrowest possible limits consistent with the logic of its principle." *In re Horowitz*, 482 F.2d 72, 81 (2d Cir. 1973) (quoting 8 Wigmore, Evidence § 2192 at 70, § 2291 at

554 (1961)); accord *Fisher v. United States*, 425 U.S. 391, 403 (1976) (“[S]ince the privilege has the effect of withholding relevant information from the fact-finder, it applies only where necessary to achieve its purpose.”).

The voluntary disclosure of privileged communications to a third party generally waives the attorney-client privilege. See *Schaeffler v. United States*, 806 F.3d 34, 40 (2d Cir. 2015). Allergan asserts that its communications with Mr. Pollock and Mr. Hanford fall under two exceptions to the third-party waiver rule, discussed in turn below. As the party asserting the privilege, defendant bears the burden of establishing that it applies. *In re Horowitz*, 482 F.2d at 82.

A. Whether Allergan’s Consultants were Necessary for the Provision of Legal Advice

In *United States v. Kovel*, 296 F.2d 918, 922 (2d Cir. 1961), the Second Circuit extended the attorney-client privilege to communications with third parties that are “necessary, or at least highly useful, for the effective consultation between the client and the lawyer.” In that case, the Court determined that communications between a client and an accountant employed by the client’s tax lawyers may be protected by the attorney-client privilege. *Id.* at 919, 921–22. The Court noted that an attorney’s use of an interpreter to translate the story of a client who speaks a foreign language would not waive privilege. *Id.* at 921–22. Thus, it reasoned, because “[a]ccounting concepts are a foreign language” to some attorneys, an accountant’s presence “while the client is relating a complicated tax story to the lawyer[] ought not to destroy the privilege.” *Id.* at 922.

Courts must narrowly construe the exception to third-party waiver recognized in *Kovel*. See *United States v. Mejia*, 655 F.3d 126, 132 (2d Cir. 2011). Communications fall within the exception if the parties had a reasonable expectation of confidentiality and the third party was “nearly indispensable or served some specialized purpose in facilitating the attorney-client

communication.” *Nat’l Educ. Training Grp., Inc. v. Skillsoft Corp.*, 1999 WL 378337, at *4 (S.D.N.Y. June 10, 1999). Thus, “a communication between an attorney and a third party does not become shielded by the attorney-client privilege solely because the communication proves important to the attorney’s ability to represent the client.” *United States v. Ackert*, 169 F.3d 136, 139 (2d Cir. 1999). Rather, the privilege extends to a communication disclosed to a third party only “if the purpose of the third party’s participation is to improve the comprehension of the communications between attorney and client.” *Id.*; accord *Ravenell v. Avis Budget Grp., Inc.*, 2012 WL 1150450, at *2 (E.D.N.Y. Apr. 5, 2012); *Exp.-Imp. Bank of the U.S. v. Asia Pulp & Paper Co.*, 232 F.R.D. 103, 113 (S.D.N.Y. 2005).

Allergan has not shown that the information Mr. Pollock and Mr. Hanford provided to its in-house and outside counsel allowed the attorneys to “understand aspects of [Allergan’s] own communications that could not otherwise be appreciated in the rendering of legal advice.” *Calvin Klein Trademark Tr. v. Wachner*, 198 F.R.D. 53, 55 (S.D.N.Y. 2000). On the contrary, neither Mr. Pollock’s or Mr. Hanford’s input was needed to explain concepts unfamiliar to Allergan’s counsel. This is not surprising. Interacting with the FDA is part of the bread and butter of a pharmaceutical company’s work.²

At oral argument, defense counsel asserted that Allergan believed the FDA was engaging in “highly unusual” behavior concerning Restasis®, and it required the expertise of Mr. Pollock

² With respect to Mr. Hanford, it was not even an attorney who recommended that he assist Allergan’s legal team on Restasis®. Mr. Lively, who is not a lawyer, not only made the referral but also often served as the conduit of information between Mr. Hanford and Allergan’s counsel—casting significant doubt on defendant’s claim that its counsel required Mr. Hanford’s input to impart effective legal advice. *See In re Grand Jury Subpoenas Dated Mar. 24, 2003*, 265 F. Supp. 2d 321, 331 (S.D.N.Y. 2003) (“[The client] would not have enjoyed any privilege for her own communications with [the consultants] if she had hired [them] directly, even if her object in doing so had been purely to affect her legal situation.”).

and Mr. Hanford to guide it through this “extremely complex regulatory situation,” involving both the FDA and Congress. But that these consultants offered Allergan assistance in navigating a difficult situation—as opposed to facilitating attorney-client communication—does not shield Allergan’s discussions with them from disclosure under *Kovel*. See *Ackert*, 169 F.3d at 139; *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmbH*, 2014 WL 7238354, at *2 (S.D.N.Y. Dec. 19, 2014); *Calvin Klein Trademark Tr.*, 198 F.R.D. at 55.

Defendant relies heavily on *In re Grand Jury*, 265 F. Supp. 2d 321, which “arguably extended the privilege the furthest.” *Ravenell*, 2012 WL 1150450, at *3. In that criminal case, the court held that “(1) confidential communications (2) between lawyers and public relations consultants (3) hired by the lawyers to assist them in dealing with the media in cases such as this (4) that are made for the purpose of giving or receiving advice (5) directed at handling the client’s legal problems are protected by the attorney-client privilege.” *In re Grand Jury*, 265 F. Supp. 2d at 331. The holding is confined to situations where a third party performs a role that is not only crucial, but “beyond the expertise of counsel.” *Ravenell*, 2012 WL 1150450, at *3 (citing *In re Grand Jury*, 265 F. Supp. 2d at 326, 330). Additionally, the case’s precedential value is likely limited to its unique context—a high-profile criminal investigation where the lawyers are attempting to counteract “the broad power of the government.” See *In re Grand Jury*, 265 F. Supp. 2d at 323, 330; *In re Chevron Corp.*, 749 F. Supp. 2d 170, 184 n.64 (S.D.N.Y. 2010) (*In re Grand Jury* judge describing the case’s holding as “very narrow”). *In re Grand Jury* does not apply to the situation here—the routine hiring of consultants to help a company improve its regulatory position.

In sum, Allergan has not shown that its attorneys’ communications with Mr. Pollock and Mr. Hanford are protected by *Kovel*. Rather than serving to translate concepts that Allergan’s lawyers were otherwise incapable of understanding, Mr. Pollock and Mr. Hanford spoke the same

language as these lawyers. Indeed, Allergan has not offered any principled way to distinguish Mr. Pollock and Mr. Hanford from any other consultant retained by a company. It thus seeks a ruling that would lead the narrow exception set forth in *Kovel* to swallow the third-party waiver rule.

B. Whether Allergan's Consultants were Functionally Equivalent to Allergan Employees

Defendant contends that its communications with Mr. Pollock and Mr. Hanford are protected by the attorney-client privilege because these consultants were “functionally equivalent” to its own employees. The “functional equivalent” exception to privilege waiver originated in *In re Bieter Co.*, 16 F.3d 929, 933–34, 939–40 (8th Cir. 1994), where the Eighth Circuit held that an individual who aided a two-person company’s development of a parcel of land was functionally equivalent to a company employee where he assisted with the project from its inception and for several years thereafter; worked out of the company’s office; was the company’s sole representative at meetings with potential tenants and local officials; appeared at public hearings on the company’s behalf; and often spoke with the company’s counsel alone. *See also United States v. Graf*, 610 F.3d 1148, 1158–59 (9th Cir. 2010).

Although several district courts within this Circuit have recognized the functional equivalent exception, the Second Circuit has yet to address it. Some district courts here have questioned whether the Court would adopt the exception given that it “has recognized very limited exceptions to privilege waiver.” *Church & Dwight Co.*, 2014 WL 7238354, at *2; *accord Homeward Residential, Inc. v. Sand Canyon Corp.*, 2017 WL 4676806, at *14 n.21 (S.D.N.Y. Oct. 17, 2017). I, too, am skeptical that the Second Circuit would adopt the exception. Assuming, however, that the exception is viable, I find that it should be construed narrowly.

Courts in this Circuit have considered the following factors, among others, to determine functional equivalency: whether the consultant exercised independent decision-making on the

company's behalf; possessed information held by no one else at the company; served as a company representative to third parties; maintained an office at the company or otherwise spent a substantial amount of time working for it; and sought legal advice from corporate counsel to guide his or her work for the company.³ See, e.g., *Narayanan v. Sutherland Glob. Holdings Inc.*, 285 F. Supp. 3d 604, 617–18 (W.D.N.Y. 2018); *Durling v. Papa John's Int'l, Inc.*, 2018 WL 557915, at *5 (S.D.N.Y. Jan. 24, 2018); *Church & Dwight Co.*, 2014 WL 7238354, at *3; *Steinfeld v. IMS Health Inc.*, 2011 WL 6179505, at *3–4 (S.D.N.Y. Dec. 9, 2011); *Am. Mfrs. Mut. Ins. Co.*, 2008 WL 5231831, at *3 (E.D.N.Y. Dec. 11, 2008); *Exp.-Imp. Bank*, 232 F.R.D. at 113–14; *Twentieth Century Fox Film Corp. v. Marvel Enters., Inc.*, 2002 WL 31556383, at *2 (S.D.N.Y. Nov. 15, 2002); *In re Copper Mkt. Antitrust Litig.*, 200 F.R.D. 213, 219 (S.D.N.Y. 2001).

For example, under the unique circumstances in *In re Copper Mkt.*, 200 F.R.D. at 215, 220, the court deemed employees of a “crisis management” public relations firm retained by a Japanese company faced with a trading scandal to be functionally equivalent to the company’s employees. The company hired the firm because it lacked experience dealing with the Western media, including the English language skills necessary to do so, as well as experience with the publicity that accompanies high-profile litigation. *Id.* at 215. In its holding, the court noted that the public relations firm had authorization to make decisions on the company’s behalf and sought advice from corporate counsel to formulate a public relations strategy. *Id.* at 219.

³ Courts often evaluate these factors in the context of a test set forth in *Exp.-Imp. Bank*: (1) “whether the consultant had primary responsibility for a key corporate job,” (2) “whether there was a continuous and close working relationship between the consultant and the company’s principals on matters critical to the company’s position in litigation,” and (3) “whether the consultant is likely to possess information possessed by no one else at the company.” 232 F.R.D. at 113.

By contrast, in *Exp.-Imp. Bank*, the court found that a corporation had waived its right to assert the attorney-client privilege over documents shared with a financial consultant hired to assist in restructuring its debt. 232 F.R.D. at 112, 114. The court reached this conclusion even though the consultant “occupied a broad role that reflected a considerable degree of responsibility,” including negotiating on the company’s behalf, helping formulate its financial strategies, and explaining its positions to creditors. *Id.* at 113. The court observed that, if it were to find the consultant functionally equivalent, it would extend the doctrine “to every situation where a financial consultant worked exhaustively to guide a company through a restructuring deal”—a result inconsistent with the attorney-client privilege’s narrow scope. *Id.* at 113–14.

Similarly, in *Church & Dwight Co.*, 2014 WL 7238354, at *1–2, the court held that employees of an outside marketing firm a company had hired to help with a product launch were not functionally equivalent to the company’s own employees. The court rejected the company’s argument that its in-house marketing team was “too small” to do the job alone and that “the complex regulatory scheme” at issue—which involved a process rarely used by the FDA—required the company to share legal advice with its consultants. *Id.* at *1–3. The court instead reasoned that the company’s use of consultants to assist “with a large and complicated product roll out” made it “no different than most companies who hire external advertising agencies.” *Id.* at *3.

Defendant asks me to follow the approach to functional equivalency in *In re Flonase Antitrust Litig.*, 879 F. Supp. 2d 454, 459–60 (E.D. Pa. 2012), where the court found that independent consultants hired by a pharmaceutical company were functionally equivalent to its employees. *See also Fed. Trade Comm’n v. GlaxoSmithKline*, 294 F.3d 141, 148 (D.C. Cir. 2002). The *In re Flonase* court rejected as “too restrictive” the approach to equivalency in cases like *Exp.-Imp. Bank* in favor of “a broad practical approach” to account for the realities of “today’s

marketplace, where businesses frequently hire contractors and still expect to be able to seek legal advice.” 879 F. Supp. 2d at 459–60 (quoting *U.S. ex rel. Fry v. Health All. of Greater Cincinnati*, 2009 WL 5033940, at *4 n.1 (S.D. Ohio Dec. 11, 2009)). Since this approach is inconsistent with my understanding of Second Circuit law, I decline to follow it and will, instead, address the facts here in light of the applicable law in this Circuit.

Here, defendant has not shown that Mr. Pollock and Mr. Hanford played such exceptional roles at Allergan that they should be treated as anything other than typical part-time consultants.⁴ As discussed above, Allergan engaged Mr. Pollock and Mr. Hanford through routine consulting agreements to enhance its regulatory strategy regarding Restasis®. Although the declarations submitted by defendant attempt to portray the consultants’ knowledge as unique and specialized, their expertise supplemented the knowledge of others at Allergan. Indeed, Allergan has its own in-house governmental affairs team. That it was too small to handle the complexities of the situation facing Restasis®, as counsel argued at oral argument, did not transform its consultants into *de facto* employees.

Defendant also has not demonstrated that either Mr. Pollock or Mr. Hanford exercised any independent decision-making for Allergan. According to defendant, both consultants “evaluate[d] legal developments and provide[d] information and advice” on issues involving the FDA. Thus, while they offered their input to those at Allergan who made decisions, they did not make decisions

⁴ With a handful of exceptions, Allergan’s privilege log entries involving Mr. Pollock are from July and August 2013—a short stint that is consistent with the role of a consultant, not an employee. While Mr. Hanford’s relationship with Allergan spanned several years, it is not clear how much of his work for the company involved Restasis® as opposed to other drugs. This motion concerns only 92 emails sent over the course of two years, which is hardly indicative of a *de facto* employee (although Mr. Hanford may have participated in other non-privileged communications). I also note that Mr. Lively declared that he “often”—as opposed to always—worked with Mr. Hanford in the same manner in which he worked with other Allergan employees.

themselves. Nor did either consultant appear on Allergan's behalf or correspond with third parties as company representatives. The consultants also worked out of their own offices (not Allergan's), communicated via the email addresses provided by their consulting firms (not Allergan), and likely served as consultants for other companies while they were assisting Allergan. Moreover, Allergan has not shown that either Mr. Pollock or Mr. Hanford was so integrated into its corporate structure that he sought and received legal advice from Allergan's counsel, rather than solely providing his input to Allergan's counsel and staff.

In conclusion, defendant has not met its burden to demonstrate that Mr. Pollock and Mr. Hanford were functionally equivalent to its own employees. Their roles, while no doubt important, are a far cry from that of the consultants in *In re Bieter*, 16 F.3d at 933–34, and *In re Copper Mkt.*, 200 F.R.D. at 215–16. As with Allergan's arguments regarding the *Kovel* exception, if I were to find otherwise, the functional equivalent test could swallow the privilege waiver rule. See *Homeward Residential, Inc.*, 2017 WL 4676806, at *14; *Church & Dwight Co.*, 2014 WL 7238354, at *3; *Exp.-Imp. Bank*, 232 F.R.D. at 114.

III. CONCLUSION

Plaintiffs' motion to compel is granted. Defendant shall produce the relevant documents within two weeks of the date of this decision.

SO ORDERED.

Dated: January 17, 2019
Brooklyn, New York

/s/ *Nina Gershon*

NINA GERSHON
United States District Judge